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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,708	04/05/2006	Chunlin Yang	FP0302 US	2047

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
06/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,708	YANG ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, 27-28 and 37-38 drawn to a tissue sealant composition, comprising a crosslinking agent, and a synthetic collagen or a synthetic gelatin, in a dry state, wherein, in the dry state, the crosslinking agent does not react with the synthetic collagen or with the synthetic gelatin, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin, thereby forming a tissue sealant composition.

Group II, claim(s) 17, 22-26 and 29-36 a tissue sealant composition, comprising a crosslinking agent, and a synthetic collagen or a synthetic gelatin, in a dry state, wherein, in the dry state, the crosslinking agent does not react with the synthetic collagen or with the synthetic gelatin, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin, thereby forming a tissue sealant composition futher comprising a matrix scaffold; wherein the matrix comprises atype of collagen, wherein the matrix comprises a reservoir containing an aqueous solution.

Group II, claim(s) 39-40, drawn to a method of producing a tissue sealant, the method comprising: drying a crosslinking agent, and a synthetic collagen or a synthetic gelatin, under conditions in which the crosslinking agent, when contacted with the synthetic collagen or the synthetic gelatin under conditions other than an environment comprising about a physiological pH, does not react with the synthetic collagen or the synthetic gelatin, thereby producing tissue sealant components in a dry state; and contacting tissue sealant components with an environment comprising about a physiological pH, whereby the crosslinker reacts with the synthetic collagen or with the synthetic gelatin, thereby producing a tissue sealant..

Group III, claim(s) 41-49, drawn to a method of producing a tissue sealant, the method comprising: mixing a and a synthetic collagen or a synthetic gelatin, under conditions in which the polymeric crosslinker does not react with the synthetic collagen or the synthetic gelatin, thereby producing a tissue sealant component mixture; and drying the tissue sealant component mixture under said conditions, thereby producing a tissue sealant in a dry state.

Group IV, claim(s) 50-54, drawn to a method of sealing a wound, comprising contacting the wound with the tissue sealant composition comprising a crosslinking agent, and a synthetic collagen or a synthetic gelatin, in a dry state, wherein, in the dry state, the crosslinking agent does not react with the synthetic collagen or with the synthetic gelatin, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin, thereby forming a tissue sealant composition.

Group V, claim(s) 55-54, drawn to a kit, comprising at least one crosslinking agent, and at least one of a synthetic collagen component or a synthetic gelatin component, wherein, upon contact in a dry state, the polymeric crosslinking agent does not react with the synthetic collagen component or with the synthetic gelatin component, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen component or the synthetic gelatin component to form a tissue sealant composition.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-V appears to be that they all relate to a tissue sealant composition comprising collagen.

However, Green et al. United States Patent No. 6,267,957 discloses a tissue sealant composition comprising collagen (column 14, lines 12-20).

Therefore the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

For Claims 1-9; applicants must select from: synthetic collagen; the synthetic gelatin. Depending on the election above, for claims 3, 8, applicants must select from: type I collagen; type III collagen. For claims 10-15 applicants must select from electrophilically activated (EA) poly(ethylene glycol) (PEG) ; an EA PEG derivative; PEG-succinimidyl propionate, PEG-succinimidyl butanoate, or PEG-succinimidyl glutarate. For claims 22-27 applicants must select from: recombinant human type III collagen, synthetic collagen, synthetic gelatin, collagen type I, collagen type II.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT B. MONDESI whose telephone number is (571)272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashed Nashaat can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Primary Examiner
Art Unit 1652